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| 09/966,147 | 09/27/2001 | Leonard G. Presta | GENENT.33CPC4C | 4067 |

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KNOBBE MARTENS OLSON & BEAR LLP
2040 MAIN STREET
FOURTEENTH FLOOR
IRVINE, CA 92614

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| EXAMINER |
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UNGAR, SUSAN NMN

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| ART UNIT | PAPER NUMBER |
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1642

DATE MAILED: 09/23/2003

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Please find below and/or attached an Office communication concerning this application or proceeding.

| | | | |
|---|--------------------------------------|---|---|
| Office Action Summary | Application No. 09/966,147 | Applicant(s) Presta et al | |
| | Examiner Ungar | Art Unit 1642 |  |
| <i>-- The MAILING DATE of this communication appears on the cover sheet with the correspondence address --</i> | | | |
| Period for Reply | | | |
| A SHORTENED STATUTORY PERIOD FOR REPLY IS SET TO EXPIRE <u>one</u> MONTH(S) FROM THE MAILING DATE OF THIS COMMUNICATION. | | | |
| <ul style="list-style-type: none"> - Extensions of time may be available under the provisions of 37 CFR 1.136 (a). In no event, however, may a reply be timely filed after SIX (6) MONTHS from the mailing date of this communication. - If the period for reply specified above is less than thirty (30) days, a reply within the statutory minimum of thirty (30) days will be considered timely. - If NO period for reply is specified above, the maximum statutory period will apply and will expire SIX (6) MONTHS from the mailing date of this communication. - Failure to reply within the set or extended period for reply will, by statute, cause the application to become ABANDONED (35 U.S.C. § 133). - Any reply received by the Office later than three months after the mailing date of this communication, even if timely filed, may reduce any earned patent term adjustment. See 37 CFR 1.704(b). | | | |
| Status | | | |
| 1) <input checked="" type="checkbox"/> Responsive to communication(s) filed on <u>Sep 27, 2001</u> | | | |
| 2a) <input type="checkbox"/> This action is FINAL. 2b) <input checked="" type="checkbox"/> This action is non-final. | | | |
| 3) <input type="checkbox"/> Since this application is in condition for allowance except for formal matters, prosecution as to the merits is closed in accordance with the practice under <i>Ex parte Quayle</i> , 1935 C.D. 11; 453 O.G. 213. | | | |
| Disposition of Claims | | | |
| 4) <input checked="" type="checkbox"/> Claim(s) <u>1-25</u> is/are pending in the application. | | | |
| 4a) Of the above, claim(s) _____ is/are withdrawn from consideration. | | | |
| 5) <input type="checkbox"/> Claim(s) _____ is/are allowed. | | | |
| 6) <input type="checkbox"/> Claim(s) _____ is/are rejected. | | | |
| 7) <input type="checkbox"/> Claim(s) _____ is/are objected to. | | | |
| 8) <input checked="" type="checkbox"/> Claims <u>1-25</u> are subject to restriction and/or election requirement. | | | |
| Application Papers | | | |
| 9) <input type="checkbox"/> The specification is objected to by the Examiner. | | | |
| 10) <input type="checkbox"/> The drawing(s) filed on _____ is/are a) <input type="checkbox"/> accepted or b) <input type="checkbox"/> objected to by the Examiner. <i>Applicant may not request that any objection to the drawing(s) be held in abeyance. See 37 CFR 1.85(a).</i> | | | |
| 11) <input type="checkbox"/> The proposed drawing correction filed on _____ is: a) <input type="checkbox"/> approved b) <input type="checkbox"/> disapproved by the Examiner. <i>If approved, corrected drawings are required in reply to this Office action.</i> | | | |
| 12) <input type="checkbox"/> The oath or declaration is objected to by the Examiner. | | | |
| Priority under 35 U.S.C. §§ 119 and 120 | | | |
| 13) <input type="checkbox"/> Acknowledgement is made of a claim for foreign priority under 35 U.S.C. § 119(a)-(d) or (f). | | | |
| a) <input type="checkbox"/> All b) <input type="checkbox"/> Some* c) <input type="checkbox"/> None of: 1. <input type="checkbox"/> Certified copies of the priority documents have been received. 2. <input type="checkbox"/> Certified copies of the priority documents have been received in Application No. _____. 3. <input type="checkbox"/> Copies of the certified copies of the priority documents have been received in this National Stage application from the International Bureau (PCT Rule 17.2(a)). | | | |
| *See the attached detailed Office action for a list of the certified copies not received. | | | |
| 14) <input type="checkbox"/> Acknowledgement is made of a claim for domestic priority under 35 U.S.C. § 119(e). a) <input type="checkbox"/> The translation of the foreign language provisional application has been received. | | | |
| 15) <input type="checkbox"/> Acknowledgement is made of a claim for domestic priority under 35 U.S.C. §§ 120 and/or 121. | | | |
| Attachment(s) | | | |
| 1) <input type="checkbox"/> Notice of References Cited (PTO-892) | | 4) <input type="checkbox"/> Interview Summary (PTO-413) Paper No(s). _____ | |
| 2) <input type="checkbox"/> Notice of Draftsperson's Patent Drawing Review (PTO-948) | | 5) <input type="checkbox"/> Notice of Informal Patent Application (PTO-152) | |
| 3) <input type="checkbox"/> Information Disclosure Statement(s) (PTO-1449) Paper No(s). _____ | | 6) <input type="checkbox"/> Other: _____ | |

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1. Claims 1-25 are pending in the application and are currently under prosecution.

Please Note: In an effort to enhance communication with our customers and reduce processing time, Group 1640 is running a Fax Response Pilot for Written Restriction Requirements. A dedicated Fax machine is in place to receive your responses. The Fax number is 703-308-4315. We encourage your participation in this Pilot program. If you have any questions or suggestions please contact Anthony Caputa, Ph.D., Supervisory Patent Examiner at 703-308-3995. Thank you in advance for allowing us to enhance our customer service. Please limit the use of this dedicated Fax number to responses to Written Restrictions.

2. Restriction to one of the following inventions is required under 35 U.S.C. § 121:

Group 1. Claims 1, 2, 4-8 are drawn to a method for inhibiting a biological activity mediated by human TrkA *in vitro*, classified in Class 435, subclass 7.1.

3. It is noted that the claims of the instant application have been determined to include linking claims. The restriction requirement among the linked inventions is subject to the nonallowance of the linking claim(s), claim 1, drawn to inhibiting a biological mediated by TrkB, *in vitro*. Upon the allowance of the linking claim(s), the restriction requirement as to the linked inventions shall be withdrawn and any claim(s) depending from or otherwise including all the limitations of the allowable linking claim(s) will be entitled to examination in the instant application. Applicant(s) are advised that if any such claim(s) depending from or including all

the limitations of the allowable linking claim(s) is/are presented in a continuation or divisional application, the claims of the continuation or divisional application may be subject to provisional statutory and/or nonstatutory double patenting rejections over the claims of the instant application. Where a restriction requirement is withdrawn, the provisions of 35 U.S.C. 121 are no longer applicable. *In re Ziegler*, 44 F.2d 1211, 1215, 170 USPQ 129, 131-32 (CCPA 1971). See also MPEP § 804.01.

Group 2. Claims 1, 2, 4-7, 9 are drawn to a method for inhibiting a biological activity mediated by human TrkB *in vitro* wherein the human TrkB comprises SEQ ID NO:2, classified in Class 435, subclass 7.1.

Group 3. Claims 1, 2, 4-7, 9 are drawn to a method for inhibiting a biological activity mediated by human TrkB *in vitro* wherein the human TrkB comprises SEQ ID NO:4, classified in Class 435, subclass 7.1.

4. It is noted that the claims of the instant application have been determined to include linking claims. The restriction requirement among the linked inventions is subject to the nonallowance of the linking claim(s), claim 1, drawn to a method for inhibiting a biological activity mediated by TrkC *in vitro*. Upon the allowance of the linking claim(s), the restriction requirement as to the linked inventions shall be withdrawn and any claim(s) depending from or otherwise including all the limitations of the allowable linking claim(s) will be entitled to examination in the instant application. Applicant(s) are advised that if any such claim(s) depending from or including all the limitations of the allowable linking claim(s) is/are presented in a continuation or divisional application, the claims of the continuation or

divisional application may be subject to provisional statutory and/or nonstatutory double patenting rejections over the claims of the instant application. Where a restriction requirement is withdrawn, the provisions of 35 U.S.C. 121 are no longer applicable. *In re Ziegler*, 44 F.2d 1211, 1215, 170 USPQ 129, 131-32 (CCPA 1971). See also MPEP § 804.01.

Group 4. Claims 1, 2, 4-7,10 are drawn to a method for inhibiting a biological activity mediated by human TrkC *in vitro* wherein the human TrkB comprises SEQ ID NO:2, classified in Class 435, subclass 7.1.

Group 5. Claims 1, 2, 4-7,10 are drawn to a method for inhibiting a biological activity mediated by human TrkC *in vitro* wherein the human TrkB comprises SEQ ID NO:4, classified in Class 435, subclass 7.1.

Group 6. Claims 1, 3-8 are drawn to a method for enhancing a biological activity mediated by human TrkA *in vitro*, classified in Class 435, 7.1.

5. It is noted that the claims of the instant application have been determined to include linking claims. The restriction requirement among the linked inventions is subject to the nonallowance of the linking claim(s), claim 1, drawn to enhancing a biological activity mediated by TrkB *in vitro*. Upon the allowance of the linking claim(s), the restriction requirement as to the linked inventions shall be withdrawn and any claim(s) depending from or otherwise including all the limitations of the allowable linking claim(s) will be entitled to examination in the instant application. Applicant(s) are advised that if any such claim(s) depending from or including all the limitations of the allowable linking claim(s) is/are presented in a continuation or

divisional application, the claims of the continuation or divisional application may be subject to provisional statutory and/or nonstatutory double patenting rejections over the claims of the instant application. Where a restriction requirement is withdrawn, the provisions of 35 U.S.C. 121 are no longer applicable. *In re Ziegler*, 44 F.2d 1211, 1215, 170 USPQ 129, 131-32 (CCPA 1971). See also MPEP § 804.01.

Group 7. Claims 1, 3-7, 9 are drawn to a method for enhancing a biological activity mediated by human TrkB *in vitro* wherein the human TrkB comprises SEQ ID NO:2, classified in Class 435, subclass 7.1.

Group 8. Claims 1, 3-7, 9 are drawn to a method for enhancing a biological activity mediated by human TrkB *in vitro* wherein the human TrkB comprises SEQ ID NO:4, classified in Class 435, subclass 7.1.

6. It is noted that the claims of the instant application have been determined to include linking claims. The restriction requirement among the linked inventions is subject to the nonallowance of the linking claim(s), claim 1, drawn to a method of enhancing a biological activity mediated by TrkC *in vitro*. Upon the allowance of the linking claim(s), the restriction requirement as to the linked inventions shall be withdrawn and any claim(s) depending from or otherwise including all the limitations of the allowable linking claim(s) will be entitled to examination in the instant application. Applicant(s) are advised that if any such claim(s) depending from or including all the limitations of the allowable linking claim(s) is/are presented in a continuation or divisional application, the claims of the continuation or divisional application may be subject to provisional statutory and/or nonstatutory

double patenting rejections over the claims of the instant application. Where a restriction requirement is withdrawn, the provisions of 35 U.S.C. 121 are no longer applicable. *In re Ziegler*, 44 F.2d 1211, 1215, 170 USPQ 129, 131-32 (CCPA 1971). See also MPEP § 804.01.

Group 9. Claims 1, 3-7,10 are drawn to a method for enhancing a biological activity mediated by human TrkC *in vitro* wherein the human TrkB comprises SEQ ID NO:2, classified in Class 435, subclass 7.1.

Group 10. Claims 1, 3-7,10 are drawn to a method for enhancing a biological activity mediated by human TrkC *in vitro* wherein the human TrkB comprises SEQ ID NO:4, classified in Class 435, subclass 7.1.

Group 11. Claims 1, 2, 5-8, 11-14 are drawn to a method for inhibiting a biological activity mediated by human TrkA *in vivo*, classified in Class 424, 130.1.

7. It is noted that the claims of the instant application have been determined to include linking claims. The restriction requirement among the linked inventions is subject to the nonallowance of the linking claim(s), claim 1, drawn to a method of inhibiting a bioactivity mediated by TrkB *in vivo*. Upon the allowance of the linking claim(s), the restriction requirement as to the linked inventions shall be withdrawn and any claim(s) depending from or otherwise including all the limitations of the allowable linking claim(s) will be entitled to examination in the instant application. Applicant(s) are advised that if any such claim(s) depending from or including all the limitations of the allowable linking claim(s) is/are presented in a continuation or divisional application, the claims of the continuation or divisional application may

be subject to provisional statutory and/or nonstatutory double patenting rejections over the claims of the instant application. Where a restriction requirement is withdrawn, the provisions of 35 U.S.C. 121 are no longer applicable. *In re Ziegler*, 44 F.2d 1211, 1215, 170 USPQ 129, 131-32 (CCPA 1971). See also MPEP § 804.01.

Group 12. Claims 1, 2, 5-7, 9, 11-14 are drawn to a method for inhibiting a biological activity mediated by human TrkB *in vivo* wherein the human TrkB comprises SEQ ID NO:2, classified in Class 424, subclass 130.1.

Group 13. Claims 1, 2, 5-7, 9, 11-14 are drawn to a method for inhibiting a biological activity mediated by human TrkB *in vivo* wherein the human TrkB comprises SEQ ID NO:4, classified in Class 424, subclass 130.1.

8. It is noted that the claims of the instant application have been determined to include linking claims. The restriction requirement among the linked inventions is subject to the nonallowance of the linking claim(s), claim 1, drawn to a method of inhibiting a bioactivity mediated by TrkC *in vivo*. Upon the allowance of the linking claim(s), the restriction requirement as to the linked inventions shall be withdrawn and any claim(s) depending from or otherwise including all the limitations of the allowable linking claim(s) will be entitled to examination in the instant application. Applicant(s) are advised that if any such claim(s) depending from or including all the limitations of the allowable linking claim(s) is/are presented in a continuation or divisional application, the claims of the continuation or divisional application may be subject to provisional statutory and/or nonstatutory double patenting rejections over the claims of the instant application. Where a restriction requirement is

withdrawn, the provisions of 35 U.S.C. 121 are no longer applicable. *In re Ziegler*, 44 F.2d 1211, 1215, 170 USPQ 129, 131-32 (CCPA 1971). See also MPEP § 804.01.

Group 14. Claims 1, 2, 5-7,10-14 are drawn to a method for inhibiting a biological activity mediated by human TrkC *in vivo* wherein the human TrkB comprises SEQ ID NO:2, classified in Class 424, subclass 130.1.

Group 15. Claims 1, 2, 5-7,10-14 are drawn to a method for inhibiting a biological activity mediated by human TrkC *in vivo* wherein the human TrkB comprises SEQ ID NO:4, classified in Class 424, subclass 130.1.

Group 16. Claims 1, 2, 5-8, 15-16 are drawn to a method for enhancing a biological activity mediated by human TrkA *in vivo*, classified in Class 424, subclass 130.1. 9.

9. It is noted that the claims of the instant application have been determined to include linking claims. The restriction requirement among the linked inventions is subject to the nonallowance of the linking claim(s), claim 1, drawn to a method of enhancing a bioactivity mediated by TrkB *in vivo*. Upon the allowance of the linking claim(s), the restriction requirement as to the linked inventions shall be withdrawn and any claim(s) depending from or otherwise including all the limitations of the allowable linking claim(s) will be entitled to examination in the instant application. Applicant(s) are advised that if any such claim(s) depending from or including all the limitations of the allowable linking claim(s) is/are presented in a continuation or divisional application, the claims of the continuation or divisional application may be subject to provisional statutory and/or nonstatutory

double patenting rejections over the claims of the instant application. Where a restriction requirement is withdrawn, the provisions of 35 U.S.C. 121 are no longer applicable. *In re Ziegler*, 44 F.2d 1211, 1215, 170 USPQ 129, 131-32 (CCPA 1971). See also MPEP § 804.01.

Group 17. Claims 1, 2, 5-7, 9, 15-16 are drawn to a method for enhancing a biological activity mediated by human TrkB *in vivo* wherein the human TrkB comprises SEQ ID NO:2, classified in Class 424, subclass 130.1.

Group 18. Claims 1, 2, 5-7, 9, 15-16 are drawn to a method for enhancing a biological activity mediated by human TrkB *in vivo* wherein the human TrkB comprises SEQ ID NO:4, classified in Class 424, subclass 130.1.

10. It is noted that the claims of the instant application have been determined to include linking claims. The restriction requirement among the linked inventions is subject to the nonallowance of the linking claim(s), claim 1 drawn to a method of enhancing a bioactivity mediated by TrkC *in vivo*. Upon the allowance of the linking claim(s), the restriction requirement as to the linked inventions shall be withdrawn and any claim(s) depending from or otherwise including all the limitations of the allowable linking claim(s) will be entitled to examination in the instant application. Applicant(s) are advised that if any such claim(s) depending from or including all the limitations of the allowable linking claim(s) is/are presented in a continuation or divisional application, the claims of the continuation or divisional application may be subject to provisional statutory and/or nonstatutory

double patenting rejections over the claims of the instant application. Where a restriction requirement is withdrawn, the provisions of 35 U.S.C. 121 are no longer applicable. *In re Ziegler*, 44 F.2d 1211, 1215, 170 USPQ 129, 131-32 (CCPA 1971). See also MPEP § 804.01.

Group 19. Claims 1, 2, 5-7,10, 15-16 are drawn to a method for enhancing a biological activity mediated by human TrkC *in vivo* wherein the human TrkB comprises SEQ ID NO:2, classified in Class 424, subclass 130.1.

Group 20. Claims 1, 2, 5-7,10, 15-16 are drawn to a method for enhancing a biological activity mediated by human TrkC *in vivo* wherein the human TrkB comprises SEQ ID NO:4, classified in Class 424, subclass 130.1.

Group 21. Claim17-18 are drawn to a method for diagnosing a pathological condition characterized by the over-expression of human TrkA, classified in Class 435, subclass 7.1.

Group 22. Claim17-18 are drawn to a method for diagnosing a pathological condition characterized by the under-expression of human TrkA, classified in Class 435, subclass 7.1.

Group 23. Claim17-18 are drawn to a method for diagnosing a pathological condition characterized by the over-expression of human TrkB, classified in Class 435, subclass 7.1.

Group 24. Claim 17-18 are drawn to a method for diagnosing a pathological condition characterized by the under-expression of human TrkB, classified in Class 435, subclass 7.1.

Group 25. Claim 17-18 are drawn to a method for diagnosing a pathological condition characterized by the over-expression of human TrkC, classified in Class 435, subclass 7.1.

Group 26. Claim 17-18 are drawn to a method for diagnosing a pathological condition characterized by the under-expression of human TrkC, classified in Class 435, subclass 7.1.

Group 27. Claim 19 are drawn to a method for diagnosing a pathological condition characterized by the over-expression of human TrkA nucleic acid, classified in Class 435, subclass 6.

Group 28. Claim 19 are drawn to a method for diagnosing a pathological condition characterized by the under-expression of human TrkA nucleic acid, classified in Class 435, subclass 6.

Group 29. Claim 19 are drawn to a method for diagnosing a pathological condition characterized by the over-expression of human TrkB nucleic acid, classified in Class 435, subclass 6.

Group 30. Claim 19 are drawn to a method for diagnosing a pathological condition characterized by the under-expression of human TrkB nucleic acid, classified in Class 435, subclass 6.

Group 31. Claim 19 are drawn to a method for diagnosing a pathological condition characterized by the over-expression of human TrkC nucleic acid, classified in Class 435, subclass 6.

Group 32. Claim 19 are drawn to a method for diagnosing a pathological condition characterized by the under-expression of human TrkC nucleic acid, classified in Class 435, subclass 6.

Group 33. Claim 20-22 are drawn to a method for diagnosing a pathological condition characterized by the over-expression of human TrkA, classified in Class 435, subclass 4.

Group 34. Claim 20-22 are drawn to a method for diagnosing a pathological condition characterized by the under-expression of human TrkA, classified in Class 435, subclass 4.

Group 35. Claim 20-22 are drawn to a method for diagnosing a pathological condition characterized by the over-expression of human TrkB, classified in Class 435, subclass 4.

Group 36. Claim 20-22 are drawn to a method for diagnosing a pathological condition characterized by the under-expression of human TrkB, classified in Class 435, subclass 4.

Group 37. Claim 20-22 are drawn to a method for diagnosing a pathological condition characterized by the over-expression of human TrkC, classified in Class 435, subclass 4.

Group 38. Claim 20-22 are drawn to a method for diagnosing a pathological condition characterized by the under-expression of human TrkC, classified in Class 435, subclass 4.

Group 39. Claim 23 is drawn to a method for treating a pathological condition characterized by the over-expression of human TrkA, classified in Class 424, subclass 130.1.

Group 40. Claim 23 is drawn to a method for treating a pathological condition characterized by the under-expression of human TrkA, classified in Class 424, subclass 130.1.

Group 41. Claim 23 is drawn to a method for treating a pathological condition characterized by the over-expression of human TrkB, classified in Class 424, subclass 130.1.

Group 42. Claim 23 is drawn to a method for treating a pathological condition characterized by the under-expression of human TrkB, classified in Class 424, subclass 130.1.

Group 43. Claim 23 is drawn to a method for treating a pathological condition characterized by the over-expression of human TrkC, classified in Class 424, subclass 130.1.

Group 44. Claim 23 is drawn to a method for treating a pathological condition characterized by the under-expression of human TrkC, classified in Class 424, subclass 130.1.

Group 45. Claims 24-25 are drawn to a method for treating a pathological condition characterized by the over-expression of human TrkA, classified in Class 514, subclass 2.

Group 46. Claims 24-25 are drawn to a method for treating a pathological condition characterized by the under-expression of human TrkA, classified in Class 514, subclass 2.

Group 47. Claims 24-25 are drawn to a method for treating a pathological condition characterized by the over-expression of human TrkB, classified in Class 514, subclass 2.

Group 48. Claims 24-25 are drawn to a method for treating a pathological condition characterized by the under-expression of human TrkB, classified in Class 514, subclass 2.

Group 49. Claims 24-25 are drawn to a method for treating a pathological condition characterized by the over-expression of human TrkC, classified in Class 514, subclass 2.

Group 50. Claims 24-25 are drawn to a method for treating a pathological condition characterized by the under-expression of human TrkC, classified in Class 514, subclass 2.

11. The inventions are distinct, each from the other because of the following reasons:

Inventions 1-50 are materially distinct methods which differ at least in objectives, method steps, reagents and/or dosages and/or schedules used, response variables, and criteria for success.

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12. Because these inventions are distinct for the reasons given above and have acquired a separate status in the art as shown by their different classification and/or recognized divergent subject matter, restriction for examination purposes as indicated is proper.

13. 9. Applicant is reminded that upon the cancellation of claims to a non-elected invention, the inventorship must be amended in compliance with 37 C.F.R. § 1.48(b) if one or more of the currently named inventors is no longer an inventor of at least one claim remaining in the application. Any amendment of inventorship must be accompanied by a diligently-filed petition under 37 C.F.R. § 1.48(b) and by the fee required under 37 C.F.R. § 1.17(h).

10. This application currently names joint inventors. In considering patentability of the claims under 35 U.S.C. § 103, the examiner presumes that the subject matter of the various claims was commonly owned at the time any inventions covered therein were made absent any evidence to the contrary. Applicant is advised of the obligation under 37 C.F.R. § 1.56 to point out the inventor and invention dates of each claim that was not commonly owned at the time a later invention was made in order for the examiner to consider the applicability of potential 35 U.S.C. § 102(f) or (g) prior art under 35 U.S.C. § 103.

11. Applicant is advised that the response to this requirement to be complete must include an election of the invention to be examined even though the requirement be traversed.

12. Any inquiry concerning this communication or earlier communications from the examiner should be directed to Susan Ungar, PhD whose telephone number is

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(703) 305-2181. The examiner can normally be reached on Monday through Friday from 7:30am to 4pm.

If attempts to reach the examiner by telephone are unsuccessful, the examiner's supervisor, Anthony Caputa, can be reached at (703) 308-3995. The fax phone number for this Art Unit is (703) 308-4242.

Any inquiry of a general nature or relating to the status of this application or proceeding should be directed to the Group receptionist whose telephone number is (703) 308-0196.

Effective, February 7, 1998, the Group and/or Art Unit location of your application in the PTO has changed. To aid in correlating any papers for this application, all further correspondence regarding this application should be directed to Group Art Unit 1642.


Susan Ungar
Primary Patent Examiner
September 11, 2003